

AMENDMENTS TO THE CLAIMS

Kindly amend the claims as follows:

Claims 1-18. (Cancelled)

Claim 19. (Currently amended) ~~|The cervical cap of claim 17,|~~ A cervical cap comprising:
(a) a cap body that is constructed to cover a patient's exocervix and prevent ingress of
sperm and fluids and comprises a cap dome that is custom-molded to substantially
completely conform to the shape of said exocervix, (b) a rim member, dimensioned to
snugly fit said exocervix, from which the cap body extends, and (c) a portion, associated
with said cap body, that is impregnated or coated with a therapeutic agent and is
constructed to release said therapeutic agent over a period of time during use of said cap,
wherein said portion comprises a removable ring that is press-fit onto said cap adjacent
said rim member.

Claim 20. (Currently amended) The cervical cap of claim ~~[[17]]~~ 19, wherein said
therapeutic agent is selected from the group consisting of microbicides, spermicides,
medications, and combinations thereof.

Claim 21. (Currently amended) The cervical cap of claim ~~[[17]]~~ 19, wherein said
therapeutic agent is an iodine complex.

Claim 22. (Currently amended) The cervical cap of claim ~~[[17]]~~ 19, wherein said
therapeutic agent functions as both a spermicide and a microbicide.

Claims 23-25. (Cancelled)

Claim 26. (Currently amended) ~~|The method of claim 24, wherein said portion comprises a removable ring and said method further comprises|~~ A method of protecting the exocervix of a female, said method comprising:

(a) applying to said exocervix a custom-molded cervical cap comprising (i) a cap body comprising a cap dome that is custom-molded to substantially completely conform to the shape of said exocervix and is constructed to cover said exocervix and prevent ingress of sperm and fluids, (ii) a rim member dimensioned to snugly fit said exocervix, and (iii) a portion comprising a removable ring, wherein said portion is impregnated or coated with a therapeutic agent and is constructed to slowly release said therapeutic agent during use of said cap;

(b) press-fitting said ring onto an outer surface of said cervical cap; and

(c) applying said portion to said cervical cap so that said portion is removable and replaceable.

Claim 27. (Currently amended) The method of claim ~~[[23]]~~ 26, wherein said therapeutic agent is selected from the group consisting of microbicides, spermicides, medications, and combinations thereof.

Claims 28. (Previously amended) A method of measuring the diameter of an exocervix of a patient comprising the steps of:

(a) providing a ring gauge comprising a plurality of ring members having different diameters and means for positioning a selected ring member onto said patient's exocervix;

(b) inserting said ring gauge into the vagina of said patient;

(c) positioning one of said ring members around said patient's exocervix and determining whether said selected rim member fits said exocervix; and

(d) repeating steps (a)-(c) with ring members having different diameters until said selected ring member fits said exocervix, with the diameter of said selected ring member corresponding to the diameter of said exocervix.

Claim 29. (Previously amended) The method of claim 28, wherein said positioning means comprises a pair of elongated members adapted to be removably and rotatably attached to one of said ring members.

Claim 30. (Previously amended) The method of claim 28, wherein said gauge further comprises means for measuring and said method further comprises the step of (e) positioning said measuring means to determine the depth of said exocervix.

Claim 31. (Previously amended) The method of claim 30, wherein said positioning means comprises a pair of elongated members adapted to be removably and rotatably attached to one of said ring members and said measuring means comprises a measuring member movably mounted on one of said elongated members.

Claim 32. (Previously amended) The method of claim 28, said method further comprising the steps of, prior to inserting said ring gauge:

(a) inserting a cervical plunger comprising a plunger member and a tube member in fluid communication with said plunger member;

(b) placing said cervical plunger on said exocervix;

(c) drawing a vacuum through said tube member to draw said exocervix against an inner surface of said plunger member; and

(d) positioning said exocervix by moving the tube member.

Claims 33-40. (Cancelled)

Claim 41. (Currently amended) The cervical cap of claim [[17]] 19, said cap further comprising a valve constructed to allow outflow from said cap body while preventing fluid flow into said cap body.

Claim 42. (Previously amended) The cervical cap of claim 41, wherein said valve is selected from the group consisting of check valves and collapsed tube valves.

Claim 43. (Previously amended) The cervical cap of claim 41, wherein said valve comprises a membrane disposed over an outer surface of said cap body.

Claims 44-46 (Cancelled)

Claim 47. (Currently amended) The cervical cap of claim [[17]] 19, wherein said portion is replaceable.

Claim 48. (Previously amended) The cervical cap of claim 47, wherein said portion is removable.

Claim 49. (Currently amended) ~~The kit of claim 33, said kit further comprising a ring gauge~~ A kit for use by a clinician in forming a custom cervical cap in situ in a patient's body, comprising a ring gauge and a rim member dimensioned to fit an exocervix, said rim member including a substantially ring-shaped surface that, when said rim member is placed on said exocervix, faces toward the opening of the patient's vagina; a curable material; and means for applying said curable material.

Claim 50. (Currently amended) ~~|The kit of claim 34, said kit further comprising a ring gauge|~~ A kit for use by a clinician in forming a custom cervical cap in situ in a patient's body, comprising a ring gauge, a rim member dimensioned to fit an exocervix, a shell member dimensioned to be mounted on said rim member, a curable material, and means for applying said curable material.

Claims 51-56. (Cancelled)

Claim 57. (Previously amended) A kit for use by a clinician in forming a custom cervical cap in situ in a patient's body comprising a rim member dimensioned to fit an exocervix, a ring gauge, a curable material, and means for applying said curable material.

Claims 58-59. (Cancelled)

Claim 60. (Currently amended) ~~|The cervical cap of claim 1|~~ A cervical cap comprising:
a rim member dimensioned to snugly fit a patient's exocervix;
a cap dome extending from said rim member to cover the exocervix and having an opening to allow fluid flow out of said cap dome, said cap dome being custom-molded to substantially completely conform to the shape of said exocervix; and
a valve associated with said opening, constructed to allow outflow while preventing flow into said cap dome, wherein said rim member and said cap dome are of different chemical compositions.

Claim 61. (Previously presented) The cervical cap of claim 60, wherein said rim member comprises MED 54220 silicone or MED 4860 silicone and said dome comprises SILASTIC 382 silicone or MED 64220 silicone.

Claim 62. (New) The cervical cap of claim 60, wherein said valve comprises a check valve sealingly positioned in said opening.

Claim 63. (New) The cervical cap of claim 62, wherein said check valve is a duckbill valve.

Claim 64. (New) The cervical cap of claim 60, wherein said valve comprises a collapsed tube valve.

Claim 65. (New) The cervical cap of claim 60, wherein said valve comprises a membrane disposed over an outer surface of said dome and sealed to said cap dome in spaced regions.

Claim 66. (New) The cervical cap of claim 65, wherein said membrane has a thickness of less than 0.5 mm.

Claim 67. (New) The cervical cap of claim 66, wherein said membrane has a thickness of less than 0.25 mm.

Claim 68. (New) The cervical cap of claim 65, wherein said membrane comprises a silicone polymer.

Claim 69 (New) The cervical cap of claim 60, wherein said rim member comprises circumferential ridges on its inner surface.

Claim 70. (New) The cervical cap of claim 60, said cap further comprising a portion that is impregnated or coated with a therapeutic agent and that is constructed to slowly release said therapeutic agent during use of said cap.

Claim 71. (New) The cervical cap of claim 70, wherein said portion is removable.

Claim 72. (New) The cervical cap of claim 71, wherein said portion is a removable ring that is press-fit onto the cap adjacent said rim member.

Claim 73. (New) The cervical cap of claim 70, wherein said therapeutic agent is selected from the group consisting of microbicides, spermicides, medications, and combinations thereof.

Claim 74. (New) The cervical cap of claim 70, wherein said therapeutic agent is an iodine complex.

Claim 75. (New) The cervical cap of claim 60, wherein said cap dome comprises a cured polymeric material.

Claim 76. (New) The cervical cap of claim 60, wherein said portion is removable.